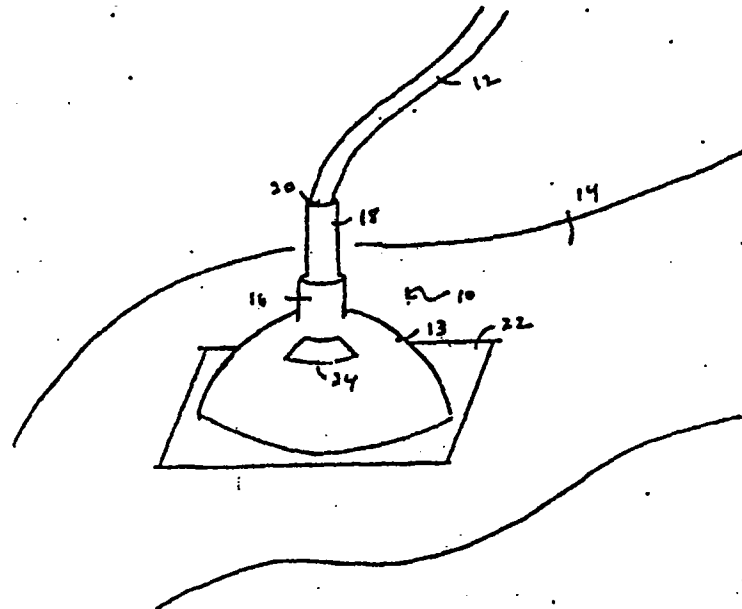




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(54) Title: RADIATION-DELIVERY DEVICE



## (57) Abstract

A method and apparatus (10) for irradiating material (14), such as tissue in a patient, is described. The method features the step of first exposing the tissue (14) with a radiation. Following the exposing step, the radiation is partially re-emitted (e.g., reflected or scattered) finally to the active. (14% ?1.n w.....:«..t...1::..i.....t..\_n\_..... -\_A

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## RADIATION-DELIVERY DEVICE.

### Background.

This invention relates to **radiation-delivery**  
5 **devices.**

**Radiation** sources, such as lasers, are used in a  
variety of medical applications because of their ability  
to generate **precise**, self-cauterizing incisions and  
locally heat tissue without contacting the patient. In  
10 particular, laser light is used in a variety of  
**dermatological** therapies, such as to remove tatoos, port-  
wine stains, and unwanted hair. In these applications,  
**radiation** is typically delivered through a fiber optic  
system to a lens, which subsequently images the **radiation**  
15 onto the region of interest. The **radiation** is absorbed  
by a **portion** of the skin or hair (e.g., the melanin or  
**blood** vessels), resulting in optical **absorption** and  
**localized** heating.

In nearly all laser-based surgical **procedures**, it  
20 is **desirable** to maximize the amount. of **radiation**  
**delivered** to the tissue, and minimize the amount of  
**radiation** which is re-emitted (e.g., **reflected** or **back-**  
**scattered**) from the tissue. This is **particularly**  
difficult to **achieve** during **dermatological procedures**, as  
25 the turbid **optical quality** of the skin tends to scatter  
incident light in all directions. In addition,  
reflection due to differences in the refractive indices  
of the skin ( $n = 1.5$ ) and **the** air ( $n = 1.0$ ) **leads** to  
further **losses**. To **compensate** for **radiation** lost **through**  
30 these processes, the operator is forced to increase the  
output power of the light source. This often decreases  
the accuracy of the procedure, or may, in fact, be  
impossible if the light source is operating at its  
maximum power output.

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manipulate laser beams to generate more **desirable** light fields for medical therapies. In U.S. Patent 5,309,339, for **example**, Webb **describes** an optical **concentrator** for  
5 **manipulating** the cross-sectional area and reducing **speckle** of an incident laser beam. In Webb's device, a **spherical** or **hemispherical** mirror is used to return laser light scattered from a diffusely reflective surface **back** onto the point of incidence. Lenses are then used to  
10 **produce** an **output** beam by collecting light from the point of incidence.

#### Summary

In general, in one aspect, the invention provides a method for irradiating a material. The method includes  
15 the step of first exposing the material with radiation (e.g., optical radiation). Following the exposing step, radiation is partially re-emitted (e.g., scattered, reflected, or both scattered and reflected) from the material. The material is then re-exposed with the re-  
20 emitted radiation. Preferably, the material is a patient's tissue. By "tissue" is meant any collection of cells or any specific organ in the patient (e.g., human skin).

The method of the invention is **carried out with an**  
25 **irradiating device** configured **receive radiation** from a **radiation delivery means**. The **radiation delivery means** **delivers radiation** from a **radiation** source to the material, and is preferably connected to a **reflective** housing. The housing includes an *opening* or surface for  
30 placement over the material and a reflective component proximal to the opening or surface. Most preferably, the radiation delivery means is a fiber optic waveguide or an articulated arm, and the radiation source is a laser.

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In preferred embodiments, the re-emitted radiation is received and reflected by a reflective device to re-expose the material. For example, the reflective device can be a reflective housing positioned proximal to the material prior to the exposing step. Preferably, the reflective housing is substantially hemispherical in shape, and the material is positioned substantially near the center of the hemisphere. Alternatively, the reflective housing is substantially elliptical in shape, and the material is positioned substantially near a focus of the ellipse. The reflective housing may **also** be substantially spherical in shape, with the opening disposed on a surface of the sphere. In still other embodiments, the reflective housing is substantially cone-shaped and includes an opening at the base of the cone. During operation, the material is positioned near this opening.

The method of the invention can also be carried out with an irradiating device which includes an optically transparent plate featuring a reflective coating on one of its surfaces. The reflective coating is disposed on the plate to transmit normally incident radiation (i.e., radiation angled at between about 80° and 100° relative to the surface of the reflective coating), receive radiation re-emitted from the material, and reflect any re-emitted radiation back onto the material. Preferably, the reflective coating **contains** a dielectric material or multiple layers of dielectric materials which exhibit angularly dependent reflective properties.

Here, by "substantially hemispherical", "substantially elliptical", or "substantially spherical" is meant a reflective housing which is shaped, respectively, in the form of a hemisphere, ellipse, or sphere so that it reflects incident light to a well-

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~~defined area. Preferably, -this-area is---no more~~ t  
few millimeters in radius. "Substantially cone-shaped"  
means at least a portion of the housing is conically  
shaped. By "center of the hemisphere" is meant the  
5 geometrical center of the sphere composed of two  
identical hemispheres. By "substantially near the  
center" or "substantially near the focus" is meant a  
position within a few millimeters of, respectively, the  
actual center or focus. "Substantially transparent" and  
10 substantially reflects" means that, respectively, at  
least 80% of the radiation is either transmitted or  
reflected.

The reflective housing preferably includes a  
reflective coating for reflecting the re-emitted  
15 radiation. The coating, for example, may be a reflective  
film, such as a metallic or dielectric film. The  
dielectric film may be reflective in only a portion of  
the electromagnetic spectrum, thereby allowing direct  
visualization of the material through the film.

20 In other preferred embodiments, the reflective  
housing features an array of grooves configured to  
reflect the re-emitted radiation. These grooves have  
reflective properties similar to those of corner cubes,  
retroreflectors, or similar optical components which  
25 reflect radiation by internal reflection. Other  
reflecting materials, such as white paint or reflecting  
tapes, may be used to reflect radiation within the  
housing. In these embodiments, the reflective housing  
may take on any shape. For example, in addition to the  
30 embodiments described above, the housing may be formed in  
the shape of a cylindrical tube, with the reflective  
material disposed on portions of the tube's inner  
surface. In this case, the opening for irradiating the  
tissue is positioned on one of the flat surfaces of the  
35 tube.

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-----In---pref rredembodiments--- the irr-adia r ev&ce - - -  
 is **used** during a medical **therapy** to **irradiate** a patient's  
 tissue. In this **case**, the **device** is **used in combination**  
 with **standard medical procedures** normally **employed** when  
 5 **radiation is delivered to tissue**. Preferably, the  
**radiation** used in the **therapy** is optical **radiation**, and  
 the **therapy** is **used to** treat human skin. **Examples of**  
 such **therapies** include **optical removal** of **tatoos**, port-  
 wine stains, **abnormal blood vessels**, **psoriatic skin**,.  
 10 **unwanted hair**, **pigmented** lesions, skin cancers and other  
 lesions treated by laser surgery, **phototherapy**,  
**photochemotherapy** or **photodynamic** therapy.

The invention has a number of **advantages**. In  
**particular**, it increases the efficiency of a laser-based  
 15 surgical procedure by treating\_ the tissue of interest  
 with radiation which is normally not utilized. **Scattered**  
**OR** reflected light, lost during **conventional procedures**,  
 is effectively "recycled" **and used to re-expose and** treat  
 the tissue. In this way, **optical** fluences can **be kept**  
 20 **relatively** low during treatment, thereby enhancing the  
**accuracy** and flexibility of the therapy.

The invention provides a gain of optical energy  
**available** to the tissue **by a** factor of up to  $(1-R)^{-1}$ ,  
 where R is the **wavelength-dependent** fraction of incident  
 25 light **re-emitted** from the tissue. **For** example, when **R** is  
 0.7 (a **typical** value for red light **re-emitted** from fair  
 skin) the energy **available** to the skin using the  
 ' **irradiation device** may be as large as three times **that**  
**available** without the **device**.

30 In addition to increasing the amount of radiation  
 available for therapy, the invention can also effectively  
 increase the exposure spot diameter of the radiation. In  
 many applications in which the "target" for therapy is  
 deep within the skin (e.g., during the **removal** of

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tattoos, port-wine stains, or hair), such a larger exposure spot diameter is advantageous.

Moreover, by collecting and then re-exposing the tissue of interest with the re-emitted radiation, the  
5 *invention* generates a more spatially uniform field during therapy. This gives the operator more control over the amount of heat delivered to the tissue, and thus improves the accuracy of the therapy.

The invention also increases the safety of laser-  
10 based therapies. Light reflected or scattered from the tissue, as well as ablated tissue which can be hazardous to the operators, is contained within a well-defined area by the irradiating device. Moreover, the device can be made small and compact, and can be used interchangeably  
15 with conventional laser-based surgical instruments. The device can additionally be fabricated with relatively inexpensive, disposable materials; a new, sterilized device can therefore be used for each procedure.

These and other *advantageb* will be apparent from  
20 the following detailed description, and from the claims.

#### Brief Description of the Drawinas

Fig. 1 is a top view of an irradiating device of the *invention* being used to irradiate a patient's skin;

Fig. 2 is a cross-sectional side view of an  
25 irradiating device in contact with the patient's skin;

Figs. 3A-3C are, respectively, cross-sectional side views of the irradiating device during initial irradiation of the skin, after radiation is initially re emitted from the skin surface, and after the re-emitted  
30 radiation is reflected off the reflective housing and back towards the skin surface;

Figs. 4A and 4B are cut-away cross-sectional side views of, respectively, a reflective housing *including* a



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ecting coating, and **a** reflective housing  
~~including an~~ array of retro-reflecting grooves;

Fig. 5 is a cross-sectional side view of an  
 irradiating device **including** a reflective housing  
 5 featuring a hemispherical top portion and a tapered  
 bottom portion;

Fig. 6 is a cross-sectional side view of an  
 irradiating device containing a reflective housing  
 featuring two **hemispherical** top portions and a straight  
 10 bottom portion;

Fig. 7 is a cross-sectional side view of an  
 irradiating device containing an elliptical reflective  
 housing;

Fig. 8 is a cross-sectional side view of an  
 15 **irradiating** device. **including** a cone-shaped-reflective  
 housing; and,

Fig. 9 is **a side view of a irradiating device**  
 featuring **a flat, optically transparent plate coated** with  
 a reflecting dielectric film.

## 20 Detailed Description

### Device Structure

Referring first to Fig. 1, an irradiating **device**  
 10 delivers radiation during a **therapy** to an **area** of--a  
 patient's tissue 14. The device 10 is configured so that  
 25 **radiation** which is normally re-emitted from the tissue  
 after **irradiation** (and is thus **wasted** during **the therapy**)  
 can be collected and imaged back onto the originally  
 irradiated area.

The device includes a fiber optic waveguide 12  
 30 coupled to a laser or other radiation source (not shown  
 in the figure). A distal end 20 of the fiber optic  
 waveguide is housed in a delivery handpiece 18 and an  
 input port 16 so that radiation from the fiber can be  
 delivered to the device 10. The input port 16 is

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13 which 'surrounds the tissue **to be irradiated and is configured to reflect radiation.** During operation, radiation is **delivered** from the fiber optic waveguide 12 to the tissue. Portions of the delivered radiation are either absorbed by the tissue, leading to radiation-induced heating, or are re-emitted from the irradiated area. The re-emitted radiation propagates away from the tissue, and is collected by the hemispherically shaped reflective housing 13. A template 22 connected to the housing 13 is used to position the device on the patient's tissue and facilitate alignment of the radiation. The template is especially useful for aligning radiation onto tissue containing rough or curved surfaces, such as the skin. The reflective housing 13 includes a transparent porthole 24 for viewing the irradiated region.

Figs. 2, 4A and 4B show cross-sectional views of the irradiation device 10 and the reflective housing 13. The delivery handpiece 18 and input port 16 connected to the housing each enclose portions of the fiber optic waveguide 12. The distal end 11 of the waveguide 12 extends into the device and is surrounded by the hemispherically shaped reflective housing 13. The housing 13 is connected to the template 22 which, in turn, is placed in contact with a patient's tissue 14. The template 22 includes an opening 21 positioned above a portion 17 of the tissue and in the center of the hemispherical reflective housing. The opening 21 and distal end 11 of the waveguide are aligned so that, during therapy, radiation from the waveguide passes through the template and onto the tissue.

The reflective housing includes a reflective coating 30 on its inner surface so that during therapy radiation scattered or reflected from the tissue is

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--collected-an • ~-- . nalsy irradiated  
portion of tissue. The reflective coating 30 can be any  
reflective material and can be made using any of a number  
of techniques known in the art. For example, the coating  
5 may be deposited as a thin reflective film on the inner  
surface of a transparent substrate 32. The coating may  
also be deposited on the substrate's outer surface.

In particular embodiments, the coating may be a  
thin metallic film composed of materials such as  
10 aluminum, silver, or gold. The reflective properties of  
these materials are dependent on the material composition  
and the film thickness, and are well known in the optical  
arts. Dielectric films may also serve as reflective  
coatings. These materials have particularly desirable  
15 reflectivities at visible and infrared wavelengths, and  
can be used to coat the inner or outer surfaces of the  
substrate material 32. Dielectric coatings have the  
additional advantage that they can be made transparent to  
visible wavelengths or radiation at certain angles of  
20 incidence; thus, when used with transparent substrates,  
these materials allow the operator to directly view the  
procedure without the need for a porthole.

The reflective housing is preferably shaped so  
that re-emitted radiation is collected and imaged onto a  
25 region contained in the originally irradiated area. In  
this way, the spatial extent of the irradiated area is  
not significantly increased by the reflective process,  
and thus the accuracy of the procedure is maintained.  
This is particularly important during therapies requiring  
30 small radiation spot sizes, such as during the treatment  
of small vascularized regions in human skin. As  
described above, the housing preferably has a  
hemispherical shape, and the irradiated region is located  
as close as possible to the center of the hemisphere. In  
35 this *configuration*, the re-emitted radiation incident on

- 10 -

the tissue is evenly distributed, and "hot spots" in the irradiated area are avoided.

In the embodiment shown in Fig. 4A, the reflective housing is hemispherical, and radiation (indicated by the  
5 arrow 33) incident on the coating 30 is reflected back towards the tissue (arrow 34) with a slight angular deviation. This angle is such that the re-exposed region of tissue lies substantially within the originally exposed area. When the coating 30 is deposited on the  
10 outer surface 35 of the substrate 32, radiation reflected back towards the tissue propagates through the substrate twice before re-exposing the tissue.

Referring now to Fig. 4B, the housing can also be made reflective by cutting right-angle grooves 36 into  
15 the transparent substrate 32. In this case, each groove 36 has two orthogonal reflective faces 35a, 35b and serves as an individual "corner cube" or "retroreflector" for reflecting the incident radiation. Preferably, an array of concentric grooves, each positioned at different  
20 cross-sectional slices of the hemisphere, are cut into the substrate. Other patterns of grooves may also be used. Preferably, in order to maximize the reflectance of the housing, the grooves are spaced together as closely as possible. For total internal reflection to  
25 occur at the air/substrate interface 38 of each groove, the substrate must be composed of a material having the appropriate refractive index. Typically, optically transparent materials, such as glasses or plastics having refractive indices greater than 1.4, are suitable. In  
30 the reflective housing 13 shown in Fig. 4B, incident radiation (indicated by the arrow 40) re-emitted from the tissue is reflected back towards its point of origin. The reflected radiation (arrow 42) is displaced by an amount equal to the propagation distance between the two  
35 orthogonal faces 35a, 35b of the groove. In this way,

- 11 -

-----the irradiated area -ol-t-is-sue-is-kept-sma-1-1--. MuLevver,  
in the embodiment shown in Fig. 4B, the radiation is  
reflected by the grooves directly back towards its point  
of origin regardless of the shape of the reflective  
5 housing. Thus, irradiation devices employing reflecting  
grooves have the additional advantage that they can be  
formed into arbitrary shapes. This is particularly  
desirable for irradiating devices configured to irradiate  
hard-to-reach areas of tissue.

10 Preferably, in the embodiments described above,  
the substrate is composed of a material which is  
transparent to the incident radiation. For example, for  
visible radiation, the substrate can be composed of  
transparent glasses, plastics, or other suitable  
15 materials *known* in the art. In particular, plastic  
materials are desirable, as they can be manufactured in  
high quantities for relatively low costs. Such materials  
are formed using techniques well-known in the art, such  
as injection molding or *machining*. Irradiation devices,  
20 and particularly those made from plastic materials, can  
be sterilized and are disposable.

In addition to the reflective surfaces shown in  
Figs. 4A and 4B, other reflective coatings and devices  
known in the art can be used with the irradiation  
25 device's reflective housing. For example, the substrate  
can be substantially composed of a reflecting material,  
thereby obviating the need for inner or outer surface  
coatings. In particular embodiments, the substrate can  
be composed of a diffusely reflecting white plastic,  
30 frosted glass, or a related material. These materials  
have lower reflectivities than metallic or dielectric-  
coated materials, and function essentially as optical  
"integrating spheres." Materials of this type have the  
advantage of irradiating an area with a particularly

- 12 -

In other embodiments, the reflecting housing may be covered on its inner or outer surface with-reflecting tape, paint, or any other material which can be used to reflect radiation, and particularly optical radiation. Preferably, the reflecting material reflects at least 80% and most preferably, at least 90% of the remitted radiation. Since the most preferred applications involve the use of optical radiation, the coating preferably exhibits the above-mentioned reflectivities for wavelengths in the range of 200 nm to 5 microns. In particularly preferred embodiments, the reflective housing is configured to reflect optical wavelengths which are typically used in dermatological applications, i.e., 500 - 1100 nm.

In still other embodiments, the template connected to the housing can be replaced with a plate which is transparent to the incident radiation. Like the template, the transparent plate is used to position the device on the patient's tissue and facilitate alignment of the radiation. The plate is particularly effective in aligning radiation onto tissue containing rough or curved surfaces, such as the skin.

Figs. 3A-3C illustrate in more detail the propagation characteristics of the radiation during a typical therapy. After being delivered from the fiber optic waveguide 12, incident radiation 19 enters the irradiation device, propagates through the opening 21 in the template 22, and irradiates the portion 17 of the patient's tissue 14. While some of the radiation is absorbed, refractive index differences between the surrounding air ( $n = 1$ ) and the tissue (typically  $n = 1.5$ ) cause a substantial fraction 19' of the incident radiation to be reflected. For example, for both black

- 13!-

radiation from 250 and 3000 nm is reflected off the stratum corneum {i.e., the skin's upper layer). This same air/skin interface also scatters incident radiation away from the skin's outer surface. Optical scattering within the skin, such as scattering from collagens in the dermis, cells in the epidermis, and other skin structures, additionally directs radiation away from the originally irradiated area.

10           Radiation propagating away from the tissue surface is collected by the reflective housing 13. Reflection off the housing redirects the re-emitted radiation 19" back towards the tissue surface, where it irradiates. the same or nearby region within the originally irradiated  
15 area. Here, radiation is again partially absorbed and partially re-emitted. Although a single reflection is indicated in the figures, radiation may undergo multiple reflections in the *housing* before being reflected back towards the originally irradiated area. As described  
20 above, to keep the irradiated area at a minimum, the reflective housing preferably has a hemispherical shape, with the irradiated region positioned at the hemisphere's center.

          In theory, this iterative process of exposing and  
25 re-exposing the tissue is repeated until all the radiation propagating in the irradiation device 10 is absorbed. In practice, however, losses due primarily to the reflectivity of the reflective housing and the fact that some components in the irradiation device (e.g., the  
30 fiber optic waveguide and the porthole) are non-reflective result in finite increases (i.e., gain) in the amount of delivered radiation. Typically, the gain due to the irradiation device represents between about 25% and 300% of the amount of radiation originally delivered  
35 to the tissue. This gain will depend on the wavelength,

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tissue properties, device reflectance, device size, and device shape.

The actual gain in the radiation energy is determined by comparing the method according to the invention to conventional means for delivering radiation to tissues. In procedures where the irradiating device is not used, the energy  $E_o$  of the radiation available for treatment is:

$$E_o = E_{incident} (1 - R_s) \quad (1)$$

where  $R_s$  is a coefficient indicative of the amount of radiation re-emitted from the tissue and  $E_{incident}$  is the energy of the incident radiation.  $R_s$  is wavelength-dependent and has a value which is less than one: a low value of  $R_s$  means that the majority of incident radiation is absorbed by the tissue, while a high value indicates a large amount of radiation re-emission. Thus, if  $R_s = .3$ , then  $E_o = 0.7 E_{incident}$  meaning that 70% of the incident light is absorbed by the tissue during treatment.

The radiation energy  $E$  available for therapy when the irradiation device is employed can be expressed mathematically as:

$$E = E_o / [1 + R_s R_m + (R_s R_m)^2 + (R_s R_m)^3 + \dots] = \frac{E_o}{(1 - R_s R_m)} \quad (2)$$

where  $R_s$  and  $E_o$  are the quantities expressed above and  $R_m$  is the collective reflectance of the reflective housing. Like  $R_s$ ,  $R_m$  is wavelength-dependent and has a value less than one. By comparing equations 1 and 2, the gain due to the irradiation device is expressed as:

$$gain = \frac{1}{(1 - R_s R_m)} \quad (3)$$

Thus, using the device of the invention, the amount of radiation available for therapy increases as the



- 15 -

increases. Most preferably, therefore, this reflectance is **made** as high as **possible**.

Table 1, shown below, lists the increases in  
5 **available** optical **radiation** as a function of the  
**radiation** wavelength and the tissue remittance for human  
skin. In all cases,  $R_m$  is 0.9 and  $R_s$  is the **reflectance**  
**value** of the skin at the optical wavelength. Increases  
in optical energy are calculated relative to conventional  
10 therapies performed without the irradiating device.

**Table 1 - Gain as a Function of Skin Remittance and Optical Wavelength**

Wavelength (nm)	Application	R	Gain	Increase in Optical Energy
510-532	vascular treatment, tattoo and hair removal	0.3	1.37	37%
585	vascular treatment	0.3	1.37	37%
694	tattoo and 'hair removal, pigment treatment	0.7	2.70	170%
1064	tattoo and hair removal	0.6	2.17	117%

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----- = - - - - - Prom **able 1**, it **ib evident** -that the gain of the radiation increases with the  $R_e R_m$  product. This product can be increased by choosing an irradiating wavelength which is re-emitted strongly by the tissue or, as  
 5 described **above**, by maximizing the reflectance of the reflective housing for the irradiating wavelength.

As is evident from the Table, optical radiation near 700 nm is subjected to a gain of approximately 170% when used in combination with the irradiating device.  
 10 This wavelength is easily obtainable using conventional light sources (e.g., ruby, dye, diode and Ti:sapphire lasers). Thus, when used with these light sources, the irradiating device effectively triples the effective amount of radiation available for therapy. optical  
 15 radiation at 1064 nm (a wavelength generated using conventional **Nd:YAG** lasers) is also subject to a high **gain** (117% **increase**) when used in **combination** with the **irradiation device**. ,

During therapy, the **distribution** of radiation  
 20 reflected from the irradiated area of tissue towards the reflective housing is typically diffuse. This is **particularly** true for skin, which is an isotropic medium functioning essentially as a Lambertian **reflector**. In **this case, the intensity of re-emitted. light varies as**  
 25 **cos(e)**, where **e** is the angle relative to the normal **vector** of the skin surface. However, the amount of light **collected by a hemispherical reflector varies as sin(e)**. Therefore, the contribution of a hemispherical reflector is most pronounced at  $e = 45^\circ$ , i.e., the angle where the  
 30 product  $\sin(e)\cos(e)$  is maximized. This means that although a large fraction of radiation is gathered at angles of between about  $0^\circ$  and  $60^\circ$  from the beam path of the incident radiation, the most significant region of **reflected radiation typically** occurs at  **$45^\circ$  from the**  
 35 angle of incidence. The amount of radiation reflected at

- 18 -

from the angle of incidence is typically negligible.  
Thus, it is particularly important for the reflective housing to have adequate reflective properties in the regions where the reflected radiation is concentrated {i.e., around  $45^{\circ}$  from the angle of incidence and preferably the region of  $0-60^{\circ}$ ). Coatings in the regions of low radiation **concentrations** (e.g.,  $90^{\circ}$ ) are less important.

Fig. 5 shows another embodiment of the invention in which the reflective **housing** 112 of the irradiation device 100 is designed to capture and reflect the re-emitted light over the important region of approximately  $\theta = 0^{\circ} - 60^{\circ}$ . The reflective housing includes a hemispherically shaped upper portion 102 and a conical lower portion 104 connected directly to a template 106. The template can be reduced in size or removed. In this **configuration**, the device, with its tapered lower portion **occupying** a relatively small area, is particularly effective in delivering radiation to hard-to-reach places.

The irradiated area 103 of tissue 105 is positioned substantially at the center of the upper portion 102 of the reflective **housing** 112. Preferably, the upper portion 102 extends at an angle of at least  $60^{\circ}$  from the angle of incidence of the input radiation. In this configuration, the reflective housing only contains reflective portions in regions where the contribution from re-emitted radiation intensity is high; no reflecting portion is present in the regions where the reflected radiation **intensity** is low, i.e., from about an angle of  $60^{\circ}$  to  $90^{\circ}$  from the angle of incidence. Note that the small amount of light which is re-emitted at these angles will be reflected by the lower portion 104 of the housing towards the upper portion 102, where it

- 19 -

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e origin-ea of  
irradiation.

The delivery handpiece 108 and input port 110 for this device are the same as those described for the embodiment of Fig. 1. Similarly, the reflective and substrate materials in this embodiment are the same as those described above. The figure shows a reflective coating 114 deposited on the *inner* surface of a substrate 115. Other types of reflective housings, such as those  
10 **containing** grooves, may also be used with the irradiation device.

Still other embodiments of the invention are shown in Figs. 6-9. In Fig. 6, an irradiating device 120 features a reflective housing 121 including first 131 and  
15 second 122 hemispherical portions and first 127 and second 124 tapered portions. The reflective housing 121 **is** in contact with a template 126 and is configured to deliver re-emitted radiation to an area 128 of tissue 110. Each portion of the housing is coated with a  
20 reflective film 125 as in previous embodiments. As indicated by the arrows 119 and 123, re-emitted radiation is reflected by the coating back towards the originally irradiated region so that the amount of radiation delivered to the area 128 is increased. In this case,  
25 the first and second hemispherical portions have different diameters; the irradiated area 128 is positioned at the coincident centers of the two hemispheres. Separating the housing into first and second hemispherical portions results in a smaller amount  
30 of the re-emitted optical intensity irradiating the non-reflective region containing the fiber optic waveguide 132 and the input port 134. This is because re-emitted radiation spatially diverges after the incident beam irradiates the tissue, and thus the spatial concentration

- 20 -

of radiatio

irradiated region 128.

Fig. 7 shows another embodiment of the invention in which the irradiating device 130 includes a reflective housing 132 shaped as an ellipse. An area 136 of tissue 138 is irradiated with an incident beam delivered by the fiber optic waveguide 140. The elliptical housing is positioned with respect to a template 134 so that one of its foci is coincident with the irradiated area 136. In this way, as indicated by the arrow 133, re-emitted radiation is returned to the originally irradiated area after being reflected multiple times by the housing.

In the embodiments shown in Figs. 6 and 7, the template connected to the housing can be replaced with a plate which is transparent to the incident radiation. Like the template, the transparent plate is used to position the device on the patient's tissue and facilitate *alignment* of the radiation. The plate is particularly effective in aligning radiation onto tissue containing rough or curved surfaces, such as the skin.

Fig. 8 shows a cross-sectional view of an irradiating device 148 where an optical fiber 150 delivering optical radiation (indicated by the arrow 152) attaches directly to a cone-shaped, diffusely reflective housing 154. The housing 154 includes an upper opening 156 which houses the fiber, and a lower opening 158 placed in direct contact with a patient's tissue 160 (e.g., the skin). The housing 154 is preferably constructed entirely of a diffusely reflecting material, such as a white plastic, to form a *highly* reflecting cavity. Alternatively, the housing may be formed from a plastic, metal, glass material coated on its inner surface with a diffusely reflecting coating (e.g., a white paint or roughened metallic coating).

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During operation, radiation emitted from the fiber 150 spatially diverges (typically at an angle of about 30°, as indicated by the dashed lines 162) until it impinges the tissue 160 and is absorbed. The height of the cone-thus determines the radiation spot size on the tissue, as the radiation's divergence and area increase with cone height. Typically the cone height is chosen to be about 1.5 cm. As described above, a portion of the radiation impinging the tissue is randomly re-emitted and propagates back towards the housing 154. There, the radiation is either reflected back onto the tissue or onto another portion of the housing. These processes increase the gain, or total amount of radiation which is absorbed by the tissue. In theory, the reflection process continues until all the incident light is either absorbed by the tissue or is sent back through the fiber 150. It is therefore desirable to increase the ratio between the areas of the lower 158 and upper 156 openings, as this will increase the actual amount of light redirected towards the tissue.

Fig. 9 shows another irradiating device 168 of the invention where the reflective housing consists of an optically transparent plate 170 coated on its upper surface with a dielectric coating 172. The plate 170, in turn, directly contacts the patient's tissue 160. As is well known in the art, the reflectivity of a dielectric coating depends on the angle and wavelength of the incident optical beam, and can be maximized or minimized by varying the thickness and refractive-index (i.e., the material composition) of the coating's dielectric layers 170a, 170b. The 'bandwidth' of the coating, i.e., the range of wavelengths or incident angles which are transmitted or reflected, depends on the refractive index and number of the layers.

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For optimum performance, the device preferably includes a narrow-band, high-efficiency coating which transmits normally incident radiation (indicated by the arrow 174) and radiation which deviates from normal by less than about  $15^\circ$ . After this radiation impinges the tissue 160, re-emitted radiation impinging the coating's bottom surface at angles greater than about  $15^\circ$  (indicated by the arrows 175), is reflected back towards the tissue by the coating to increase the gain. As is described above, re-emitted radiation typically leaves the tissue at an angle of about  $45^\circ$ . This process of reflecting re-emitted radiation continues until all the radiation is either absorbed by the tissue or is transmitted through the coating.

Other embodiments of the irradiating device of Fig. 9 are also possible. For example, the dielectric coating can be on the bottom surface of the glass plate. The plate can also be attached directly to a faceplate or handpiece for ease of use.

## Therapies and Other Applications

The irradiation device can be used in combination with any known radiation-based therapy to increase the gain of the radiation. Examples of such therapies include optical removal of tattoos, port-wine stains, abnormal blood vessels, psoriatic skin, unwanted hair, pigmented lesions, skin cancers and other lesions treated by laser surgery, phototherapy, photochemotherapy or photodynamic therapy. Additional radiation-based therapies, particularly those used in dermatology, are described in Honigsmann et al., Dermatology in General Medicines, 3rd edition, T.B. Fitzpatrick et al. (eds.) 1728-1754 (1987), the contents of which are incorporated herein by reference.

During therapy, the opening of the template or the transparent plate is placed over the area to be



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--- d according to  
standard procedures used in the optical and medical arts.

Because the effective amount of radiation which  
exposes the skin is increased using the irradiation  
5 device, it may be necessary to decrease the amount of  
radiation used during therapy. Typically, the fluence of  
the radiation is between about 0.1 and 100 W/cm<sup>2</sup>. The  
spatial intensity profile of the radiation can be  
adjusted to vary the amount of radiation-induced heat  
10 delivered to the region of interest. Radiation spot  
diameters of between 10 microns and 1 cm are typically  
used.

A laser is the preferred light source for optical  
radiation. The laser is chosen according to the desired  
15 optical wavelength. Preferred lasers include ion, dye,  
solid-state (e.g., Nd:YAG, Nd:YLF, Ti:Sapphire) holmium,  
CO<sub>2</sub>, metal-vapor, excimer, and diode lasers. Other light  
sources, such as fluorescent bulbs, may also be used.  
The light source may be continuous-wave or pulsed.

20 The irradiation device can also be used in non-  
medical applications to increase the gain of the incident  
radiation. For example, the device can be used with a  
laser to cut or process materials. The device may also  
be used to drive photochemical reactions in certain  
25 materials, such as *light-sensitive* films.

Still other embodiments are within the scope of  
the following claims.

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CLAIMS:

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1. A method for irradiating a material, said  
method comprising:  
    **exposing** said material with **radiation**, the  
    **radiation**, following said **exposing**, being partially re-  
5   **emitted** from the material, and  
    **re-exposing** the material with the **re-emitted**  
    **radiation**.
2. The method of claim 1, wherein the re-emitted  
    **radiation is** reflected, **scattered**, or reflected and  
10 scattered from the material.
3. The method of claim 1; wherein the **re-emitted**  
    **radiation** is reflected by a reflective device to re-  
    **expose** the material.
4. The method of claim 3, wherein the reflective  
15 **device is** a reflective housing positioned **proximal** to the  
    material.
5. The method of claim 4, wherein the reflective  
    housing is comprised by an irradiating device placed  
    proximal to the material prior to said exposing.
- 20       6. The method of claim 4, wherein the reflective  
    housing is substantially hemispherical in shape, and the  
    material is positioned substantially near the center of  
    the hemisphere.
7. The method of claim 4, wherein the reflective  
25 housing is substantially elliptical in shape, and the  
    material is positioned substantially near a focus of the  
    **ellipse**.

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. The method of claim 4, wherein the reflective housing is substantially cone-shaped and comprises a bottom opening, and the material is positioned near the bottom opening.

5           9. The method of claim 4, wherein the reflective housing is an optically transparent plate comprising a reflective coating which is *substantially* transparent to normally incident radiation and substantially reflects radiation incident at an angle, and the material is  
10 positioned in contact with a surface of the transparent plate.

10. The method of claim 4, wherein the reflective housing comprises a reflective coating for reflecting the re-emitted radiation.

15           11. The method of claim 4, wherein said **reflective** housing comprises an array of grooves configured to reflect the re-emitted radiation.

12. The method of claim 1, wherein the **radiation** is optical radiation.

20           13. An irradiating device for delivering radiation to a material, comprising  
a reflective housing configured to receive radiation from a radiation delivery 'means, said housing comprising-an opening or surface for placement over a  
25 material and a reflective component proximal to said opening or surface, said reflective housing being shaped to receive radiation re-emitted from the material *and* reflect the re-emitted radiation back onto the material.

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14. The irradiating device of claim 13, wherein said reflective component is a reflective film.

15. The irradiating device of claim 14, wherein said reflective film comprises a metallic or dielectric material.

16. The irradiating device of claim 13, wherein said reflective component is an array of grooves formed in said reflective housing.

17. The irradiating device of claim 13, wherein said reflective housing is substantially hemispherical in shape and said opening is positioned at a center of the hemisphere.

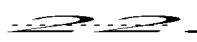
18. The irradiating device of claim 13, wherein said reflective housing is substantially elliptical in shape and said opening is positioned at a foci of the ellipse.

19. The irradiating device of claim 13, wherein said reflective housing is substantially spherical in shape and said *opening* is disposed on a surface of the sphere.

20. The irradiating device of claim 13, wherein said reflective housing is substantially conical in shape and said opening is positioned at a base of the cone.

21. The irradiating device of claim 13, wherein said radiation delivery means is a fiber optic waveguide or an articulated arm.

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 The device or claim 15, wherein -  
said radiation source is a laser.

23. An irradiating device for delivering radiation to a material, comprising  
5 an optically transparent plate comprising a reflective coating on a surface, said reflective coating being disposed on the plate to transmit normally incident radiation from a radiation delivery means, receive radiation re-emitted from a material, and reflect re-  
10 emitted radiation incident on the coating at an angle back onto the material.

24. The irradiating device of claim 23, wherein the reflective coating comprises a dielectric material.

25. The irradiating device of claim 24, wherein  
15 the reflective coating comprises multiple layers of dielectric materials.

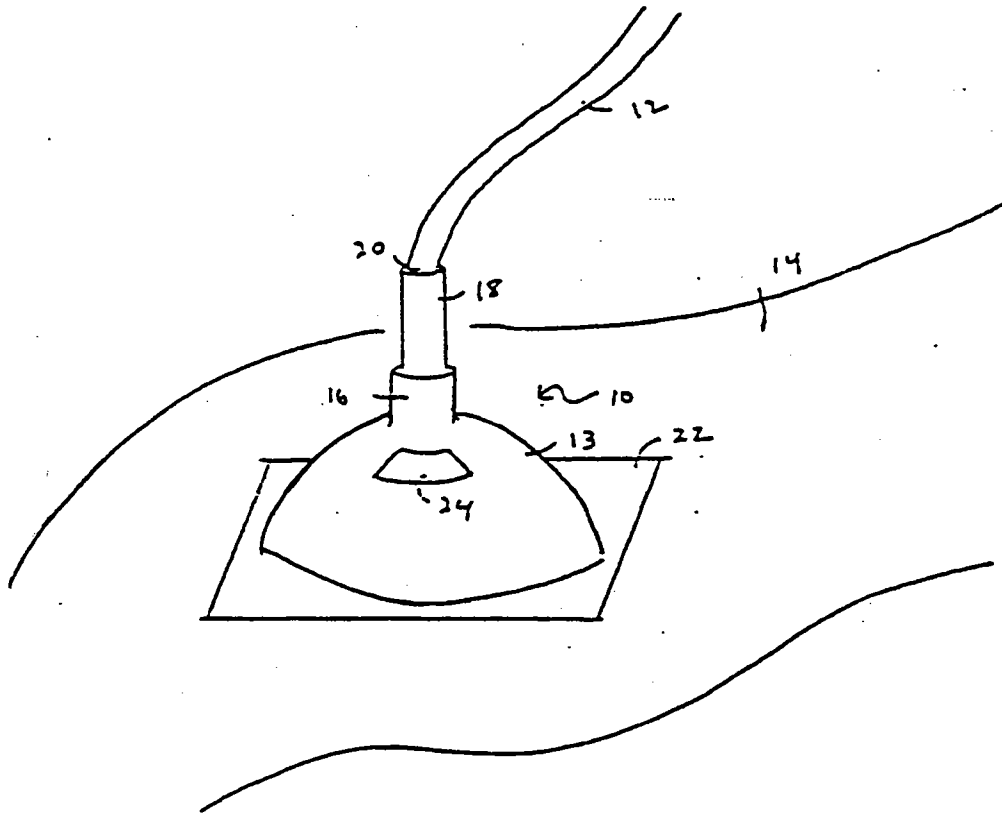


Fig. 1

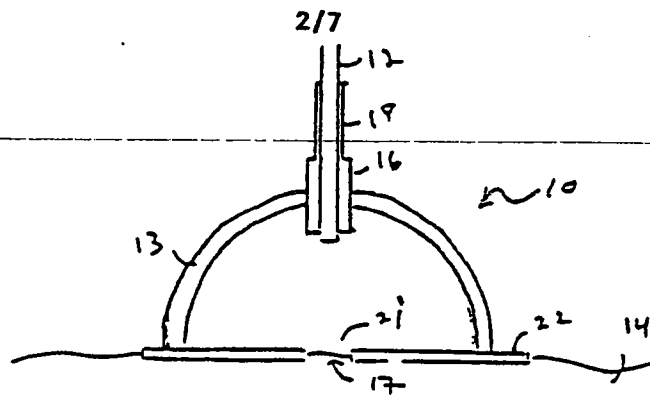
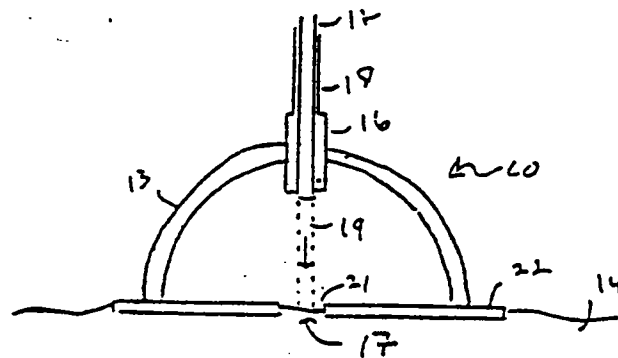


Fig. 2



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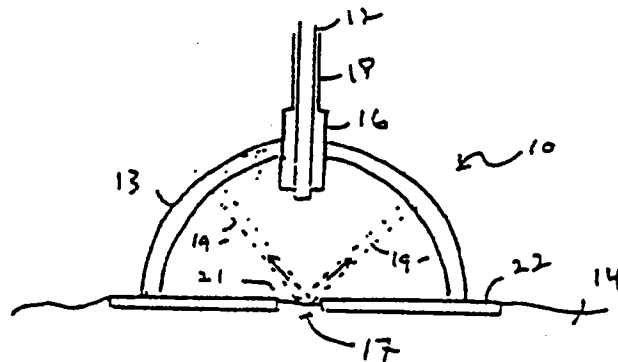


Fig. 3B

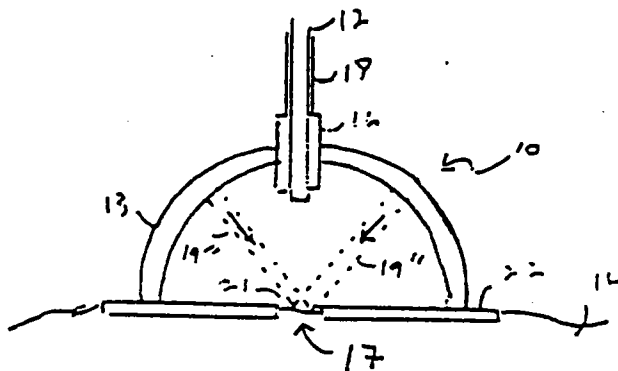
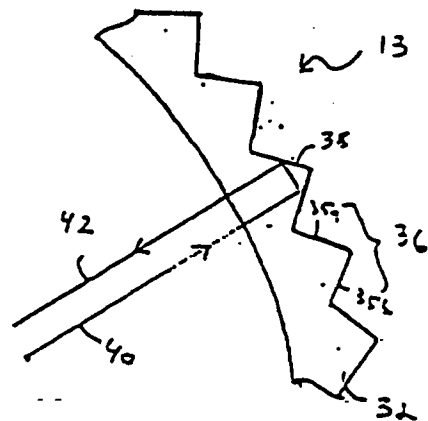
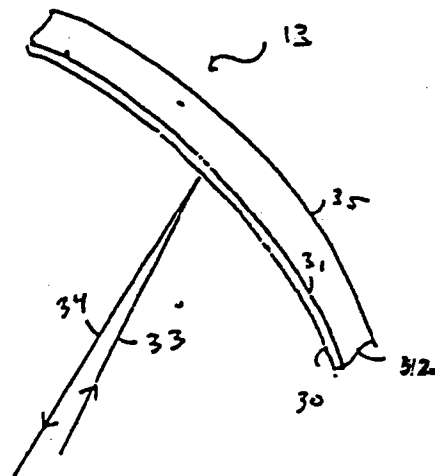
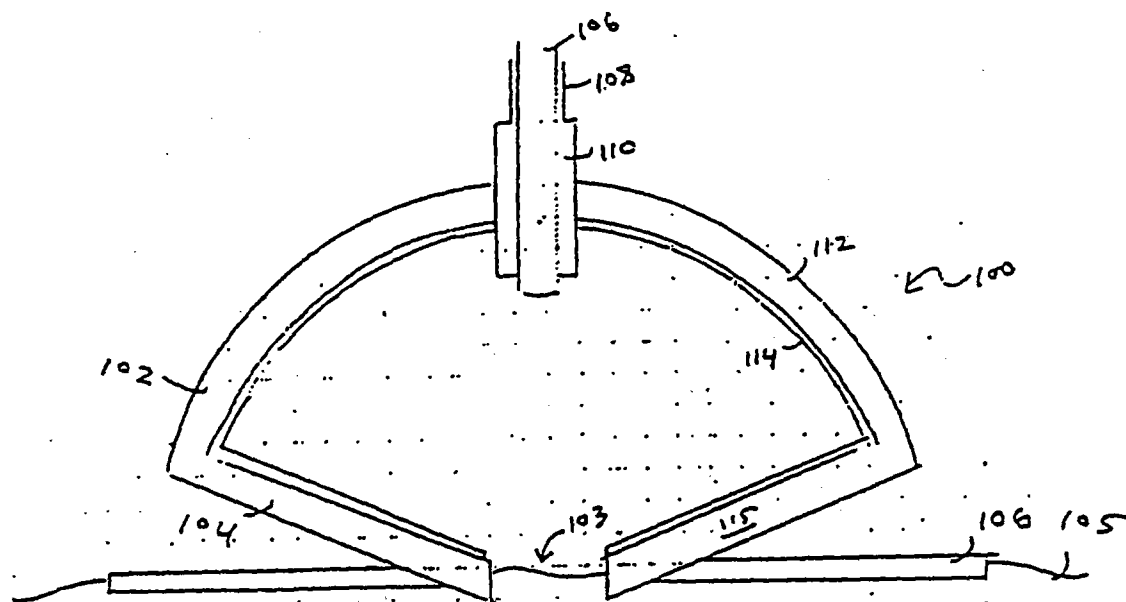


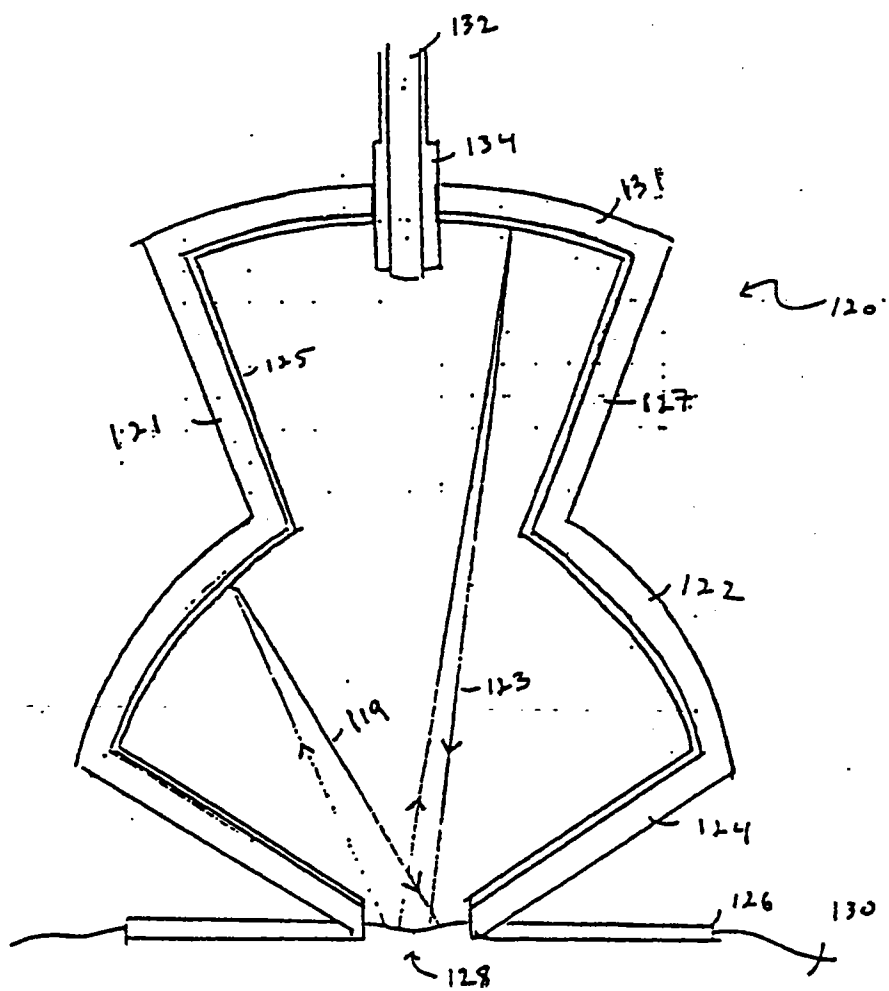
Fig. 3C

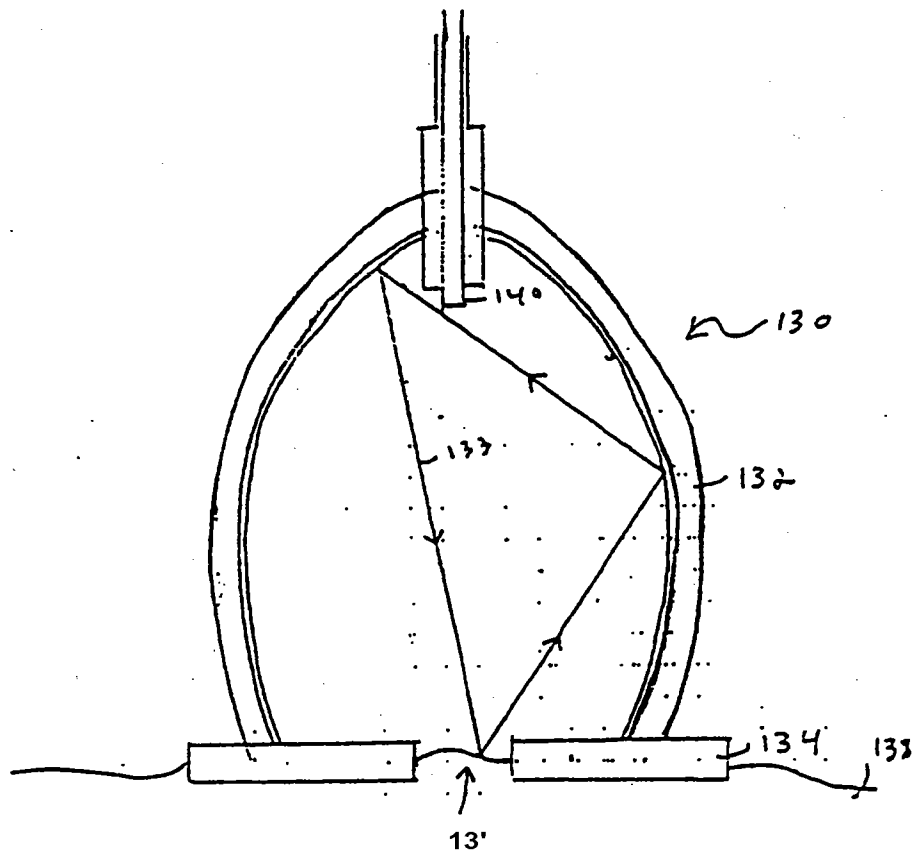


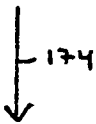
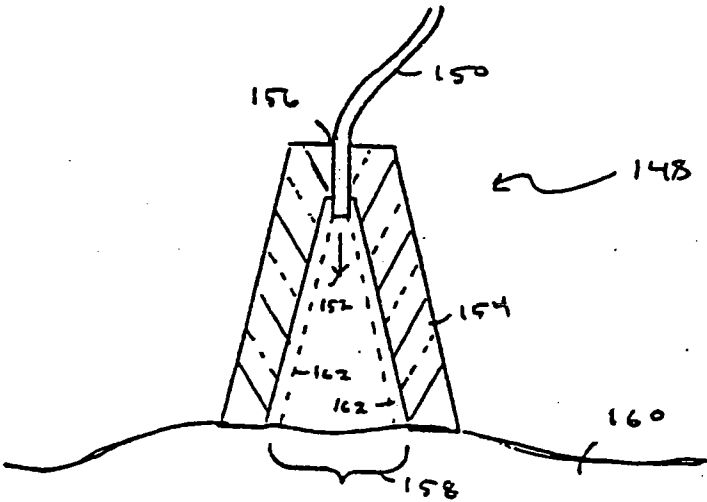




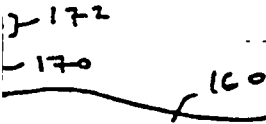
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## A. CLASSIFICATION OF SUBJECT MATTER

ECM: A61B 6100; A61N 1100

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NONE

## DOCUMENT'S CONSIDERED TO BE RELEVANT

M	Citation of document, with indication, where appropriate, of the relevant peeweels!	Relevant to claim No.
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	US 5,380,317 A (EVERETT at al.) 10 January 1995, entire document.	1-22
	US 5,108,388 A (TROKEL) 28 April 1992, entire document.	1-22
	US 3,527,932 A (THOMAS) 16 November 1967, entire document.	1-22
X,P	US 5,505,726 A (MESEROL) 09 April 1996, entire document.	23-25

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